510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k102751

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose from the fingertip

D. Type of Test:

Quantitative, amperometric, electrochemical biosensor, Glucose Oxidase

E. Applicant:

CERAGEM Medisys Inc.

F. Proprietary and Established Names:

LabonaCheck Gluppy Blood Glucose Monitoring System

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1345	Class II	CGA, glucose oxidase, glucose	Clinical Chemistry (75)
21 CFR § 862.1345	Class II	NBW, system, test, blood glucose, over the counter	Clinical Chemistry (75)
21 CFR § 862.1660	Class I, reserved	JJX, single (specified) analyte controls (assayed and unassayed)	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:

   The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

   The LabonaCheck® Gluppy Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The LabonaCheck® Gluppy Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes or for neonatal use.

   The LabonaCheck® Gluppy Blood Glucose Test Strips are for use with the LabonaCheck® Gluppy Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

   The LabonaCheck® Gluppy Control Solution is for use with the LabonaCheck® Gluppy Blood Glucose Monitoring System as a quality control check to verify that the meter and test strips are working together properly.

3. Special conditions for use statement(s):

   For over-the-counter use.

   Not for neonatal use, nor for screening for or diagnosis of diabetes mellitus.

   Not for use on critically ill patients, patients in shock, dehydrated patients or hyper-osmolar patients.

   For single patient use only and should not be shared.

4. Special instrument requirements:

   LabonaCheck Gluppy Glucose Meter

I. Device Description:

The LabonaCheck Gluppy Blood Glucose Monitoring System consists of the

LabonaCheck Gluppy Glucose Meter, LabonaCheck Gluppy Blood Glucose Test Strips with Code Key, LabonaCheck Gluppy Control Solution 1 and Control Solution 2, and a Lancing device. Control Solution 1 and Control Solution 2 are required but not included with the meter. Control Solution 1 and Control Solution 2 are always provided as a set.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bionime Rightest Blood Glucose Monitoring System, Model GM100

2. Predicate 510(k) number(s):

   k081451

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate (k081451)
Indications for Use	Same	Quantitative measurement of glucose in capillary whole blood
Testing Site	Fingertip only	Fingertip, palm, and forearm
Detection Method	Same	Amperometry
Enzyme	Same	Glucose Oxidase
Mediator	Same	Potassium ferricyanide
Measuring Range	Same	20 - 600 mg/dL
Operating Temperature Range	Same	10 – 40° C
Differences		
Item	Candidate Device	Predicate (k081451)
Sample Volume	1.0 µL	1.4 µL
Coding	Code key required	No code
Reaction Time	5 seconds	8 seconds
Hematocrit Range	20 – 60%	30 – 55%
Operating Humidity Range	10 – 80%	10 – 90%
Memory	500 results with date and time	10 results with date and time

K. Standard/Guidance Document Referenced (if applicable):

1. ISO 15197: *In vitro* diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

2. ISO 14971: 2007: Medical devices – application of risk management to medical devices.
3. EN 13612:2002: Performance evaluation of in vitro diagnostic medical devices
4. EN 13640: 2002: Stability testing of in vitro diagnostic medical devices
5. EN 61010-2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
6. IEC 61010-1:2001: Safety requirements for electrical equipment for measurement, control, and laboratory use
7. CLSI EP5-A: Evaluation of precision performance of clinical chemistry devices
8. CLSI EP6-A: Evaluation of the linearity of quantitative measurement procedures: a statistical approach
9. CLSI EP7-A: Interference testing in clinical chemistry
10. CLSI EP9-A: Method comparison and bias estimation using patient samples

L. Test Principle:

The test is based on electrochemical biosensor technology and the principle of capillary action. The glucose oxidase and potassium ferricyanide in the strip react with the glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Within-run precision was evaluated by analyzing venous whole blood samples spiked to five different glucose concentrations. The hematocrit of all samples was between 35 and 50%. Five different lot numbers of test strips and ten meters were used in the study and each of the samples was measured ten times per strip lot number per meter for a total of 100 measurements per glucose concentration. The samples were analyzed by one operator in one day. Of the five strip lots that were evaluated, the following three lots represent typical performance:

Test Strip Lot 1

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
n	20	20	20	20	20
Mean (mg/dL)	42.6	98.8	135.7	235.5	332.0
Std Dev (mg/dL)	1.8	3.1	4.4	8.0	8.7
CV (%)	4.1	3.1	3.3	3.4	2.6

Test Strip Lot 2

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400
N	20	20	20	20	20
Mean (mg/dL)	40.0	98.0	135.6	233.7	328.8
Std Dev (mg/dL)	1.7	3.2	4.6	6.0	8.5
CV (%)	4.3	3.2	3.4	2.6	2.6

Test Strip Lot 3

Glucose conc.(mg/dL)	30-50	51-110	111-150	151-250	251-400
N	20	20	20	20	20
Mean (mg/dL)	41.3	99.4	139.9	236.0	326.8
Std Dev (mg/dL)	1.7	3.7	4.9	7.4	8.3
CV (%)	4.0	3.7	3.5	3.2	2.5

Day to day precision was evaluated by analyzing control samples at three different concentrations. Three lot numbers of test strips (one per glucose level) and ten meters were used in the study. There were 20 operators and each of the control levels was measured once per day over twenty days for each of the ten meters. In total, 200 measurements were taken for each of the three levels. Results are summarized below:

Test Strip Lot 1

Control Range (mg/dL)	30-50	96-144	280-420
N	80	60	60
Mean (mg/dL)	41.6	128.8	341.8
Std Dev (mg/dL)	1.8	4.4	10
CV (%)	4.4	3.4	2.9

Test Strip Lot 2

Control Range (mg/dL)	30-50	96-144	280-420
n	60	60	80
Mean (mg/dL)	41.9	128.3	344.8
Std Dev (mg/dL)	1.7	4.4	7.6
CV (%)	4.1	3.4	2.2

Test strip Lot 3

Control Range (mg/dL)	30-50	96-144	280-420
n	60	80	80
Mean (mg/dL)	41.2	128.2	343.2
Std Dev (mg/dL)	1.8	4.3	10.7
CV (%)	4.4	3.3	3.1

b. Linearity/assay reportable range:

The sponsor evaluated the linearity of the meter by preparing a series of 9 glucose samples, following the dilution scheme in CLSI EP6-A, and producing target values of 13, 88, 162, 237, 311, 386, 462, 535, and 610 mg/dL.

Each of the nine levels was analyzed five times using two lots of test strips. All samples were also tested on the YSI 2300 analyzer. Linear regression of the data produced the following:

Strip Lot	Slope	Intercept	Corr Coeff (r^2)
1	1.047	-4.5	0.996
2	1.032	0.99	0.995

The results of the study support the sponsor's claimed glucose measurement range of 20 – 600 mg/dL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The LabonaCheck Gluppy Blood Glucose Monitoring System is traceable to the YSI 2300 Glucose analyzer which is calibrated using the YSI 2747 Glucose Standard which is a NIST traceable glucose standard.

Test strip shelf-life stability (closed vial) was assessed in an accelerated study with real time studies ongoing. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 18 months when stored at 2 - 30° C.

Test strip in-use stability (open vial) was assessed in an accelerated study with real time studies ongoing. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of four months when stored at 2 - 30° C.

Control shelf-life stability (closed vial) was assessed in real-time studies. The

protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the claimed shelf life of 18 months when stored at 2 - 30° C.

Control in-use stability (open vial) was assessed in real-time studies. The protocols and acceptance criteria were reviewed and found to be acceptable. The testing supported the open vial stability of four months when stored at 2 - 30° C.

d. Detection limit:

The measuring range of the device is 20 - 600 mg/dL. This range was validated by the linearity study (M.1.b).

e. Analytical specificity:

The sponsor performed interference studies in accordance with CLSI EP7-A. Testing was performed in parallel (control samples vs. test samples) to minimize the effects of glucose metabolism. Whole blood was drawn into K_3-EDTA anticoagulant tubes from healthy volunteers who were not on any medications. The glucose levels tested were 64, 151, and 257 mg/dL. The highest level was achieved by spiking. A low and high concentration of each potential interferent was then tested at each glucose level. The following substances were found not to interfere at the concentrations listed:

Substance	**No interference up to:**
Acetaminophen	6 mg/dL
Ascorbic Acid	4 mg/dL
Bilirubin	4 mg/dL
Cholesterol	300 mg/dL
Creatinine	10 mg/dL
Dopamine	1.0 mg/dL
Galactose	100 mg/dL
Gentisic Acid	2 mg/dL
Glutathione	3 mg/dL
Hemoglobin	20 g/dL
Hydrogenated Starch Hydrolysates	100 mg/dL
Ibuprofen	40 mg/dL
Isomalt	100 mg/dL
Lactitol	100 mg/dL
L-Dopa	4 mg/dL
Maltitol	100 mg/dL
Maltose	100 mg/dL
Mannitol	800 mg/dL
Metformin	4 mg/dL
Methyldopa	1.0 mg/dL

Substance	No interference up to:
Salicylic Acid	50 mg/dL
Sodium	150 mmol/L
Sorbitol	100 mg/dL
Tolazamide	5 mg/dL
Tolbutamide	64 mg/dL
Triglyceride	1500 mg/dL
Uric Acid	10 mg/dL
Xylitol	100 mg/dL
Xylose	100 mg/dL

The sponsor has the following limitations in their labeling:

- High concentrations of dopamine, methyldopa, and Tolazamide may cause inaccurate test results.
- Triglyceride above 1,500 mg/dL may cause inaccurate test results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

For the user performance study, 200 participants collected and tested their own fingerstick sample in single measurements on the LabonaCheck Gluppy BGMS. Please see section M.3.c for the user performance study. Within five minutes, a second fingerstick sample was collected from each participant by a healthcare professional for the system accuracy study and was tested on the YSI 2300 reference analyzer. An additional 20 contrived samples (ten greater than 388 mg/dL and ten less than 56 mg/dL) were analyzed for the system accuracy study only. Low concentrations were achieved by allowing samples to glycolyze and high concentration samples were achieved by spiking.

System Accuracy Study (n = 220)

System accuracy results vs. YSI for glucose concentrations <75 mg/dL

Within ±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
21/35 (60%)	30/35 (86%)	35/35 (100%)

System accuracy results vs. YSI for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ± 10%	Within ± 15%	Within ±20 %
106/185 (57%)	159/185 (86%)	183/185 (99%)	185/185 (100%)

Linear regression - technician vs. YSI

	Line equation	95% CI slope	95% CI intercept	r	n
Strip Lot 1	y = 1.05 x – 5.9	1.03 to 1.07	-9.4 to -2.5	0.9974	50
Strip Lot 2	y = 0.97 x + 0.2	0.93 to 1.00	-5.3 to 5.7	0.9908	50
Strip Lot 3	y = 1.00 x + 0.1	0.97 to 1.03	-4.4 to 4.5	0.9949	50
Strip Lot 4	y = 1.01 x – 4.1	0.95 to 1.06	-13.8 to 5.6	0.9800	50
Strip Lot 5	y = 1.04 x + 7.1	0.99 to 1.09	-11.2 to 25.4	0.9950	20
Combined	y = 1.04 x – 5.2	1.02 – 1.05	-8.3 to -2.2	0.9928	220

b. Matrix comparison:

Not applicable. Only fresh capillary blood samples from the finger may be used with this device.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

For the user performance study, 200 participants collected and tested their own fingerstick sample in single measurements on the LabonaCheck Gluppy BGMS. Within five minutes, a second fingerstick sample was collected from each participant for the system accuracy study and was tested on the YSI 2300 reference analyzer. An additional 20 contrived samples (ten greater than 388 mg/dL and ten less than 56 mg/dL) were analyzed for the system accuracy study only. Please see section M.2.a for a description of the system accuracy study and its results.

User performance study (n = 200)

User accuracy results vs. YSI for glucose concentrations <75 mg/dL

Within ±5 mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
18/25 (72%)	24/25 (96%)	25/25 (100%)

User accuracy results vs. YSI for glucose concentrations ≥ 75 mg/dL

Within ±5%	Within ± 10%	Within ± 15%	Within ±20 %
129/175 (74%)	163/175 (93%)	171/175 (98%)	175/175 (100%)

Linear regression - user vs. YSI

	Line equation	95% CI slope	95% CI intercept	r	n
Strip Lot 1	y = 1.06 x -3.8	1.04 to 1.09	-7.6 to 0.1	0.9969	50
Strip Lot 2	y = 1.03 x -1.5	1.01 to 1.04	-4.0 to 1.1	0.9983	50
Strip Lot 3	y = 0.99 +2.3	0.96 to 1.01	-1.7 to 6.3	0.9958	50
Strip Lot 4	y = 1.01 x -4.2	0.95 to 1.06	-13.1 to 4.8	0.9830	50
Combined	y = 1.02 x -1.4	1.00 – 1.04	-4.2 to 1.4	0.9922	200

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Expected blood glucose levels for people without diabetes (referenced from the American Diabetes Association, Diabetes Care, January 2012; vol. 35 no. Supplement 1 S11-S63

Time	**Range (mg/dL)**
Before a meal	< 100
Two hours after meals	< 140

N. Instrument Name:

LabonaCheck Gluppy Glucose Meter

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional measurements.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ☐ No ☐

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ☐ No ☐

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ☐ No ☐

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with fresh capillary whole blood from the finger which is applied directly to the test strip.

5. Calibration:

   Each vial of strips contains a Code Key which is used to code the meter before use.

6. Quality Control:

   Controls are not included in the starter kit, but the labeling explains how users can obtain two levels of controls. The labeling also provides recommendations on

when to test control materials. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is instructed to repeat the control test. If the user continues to get out of range results, they are instructed not to use the system and to contact technical service.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit study: The effect of different hematocrit levels was evaluated using venous whole blood samples with hematocrit levels across the claimed range and altered to glucose concentrations from 23 – 479 mg/dL. There were five measurements for each combination of glucose concentration and hematocrit level. The results demonstrated that the LabonaCheck Gluppy Blood Glucose Monitoring System produces accurate results over the claimed hematocrit range of 20 – 60%.

2. Altitude study: A study was conducted to evaluate the effect of altitude on the device. In this evaluation, venous blood at glucose concentrations of approximately 100, 200, and 300 mg/dL was tested using a decompression chamber to simulate the effects of altitude. Three lots of test strips and three meters were used. Each blood sample was also tested by the YSI 2300 analyzer. The meter readings obtained were compared to the YSI method and the percent bias was determined at each level against the YSI results. The results demonstrated that the LabonaCheck Gluppy Blood Glucose Monitoring System produces accurate results at altitudes up to 10,000 feet.

3. Temperature and humidity studies: In this study, three test strip lots were tested on three meters at three glucose concentrations (approximately 45, 120, and 300 mg/dL) at twelve combinations of temperature and humidity. Each combination of environmental conditions / glucose concentration / meter was tested in replicates of three. The temperatures tested ranged from a low of 10.2° C to a high of 41.1° C. The relative humidity tested ranged from 10.2% - 86.3%. Glucose concentrations were verified by the YSI reference method. The bias relative to the reference method was acceptable to support the claim that temperatures from 10 – 40° C (50 – 104° F) and relative humidity from 10 – 80% do not significantly affect the glucose results.

4. Infection Control Studies. The Ceragem Medisys LabonaCheck Gluppy Blood Glucose Monitoring System is intended for single-patient use only. Disinfection efficacy studies were performed on the materials comprising the meter and lancing device by an outside commercial testing facility demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, CaviWipes (EPA Registration Number 46781-8). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for the meter and lancing device after 1825 cleanings and 1825 disinfection steps with CaviWipes. The robustness studies were designed to

simulate 5 years of single-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

5. Electromagnetic Compatibility (EMC) Testing was evaluated and certified by TUV and a test report dated September 11, 2010 was submitted stating that the device met all of the requirements of the following standards:

   EN 61326: 1997 + A1: 1998 + A2: 2001 + A3: 2003
   EN 61326-2-6: 2006
   EN 60601-1-2: 2007
   EN 55011: 2007 Group 1 Class B

6. Readability Assessment: The sponsor performed a reading level assessment of the labeling. The Flesch-Kincaid results were as follows:

User manual:	Grade level 7.5
Test strip insert:	Grade level 7.8
Control solution insert:	Grade level 7.8

7. Usability Study: A usability study was performed to assess the readability of the labeling by recruiting untrained lay users who were provided with the test kit and labeling. These lay users also completed a questionnaire regarding the clarity of the instructions and the ease of use of the device. The majority of the users responded that they understood the instructions and were able to successfully operate the device.

8. The sponsor provided the results of the device software testing including a hazard analysis, traceability analysis, validation and verification testing, and release level history which were reviewed and found to be adequate.

9. The Toll-free Customer Service number available 24 hours a day, 7 days a week is 1-800-903-9333.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.